European Medicines Agency

EMEA/MB/472819/2009
1 October 2009

Status report on EudraVigilance implementation
Human medicinal products

Background note

This document provides information on the implementation status of EudraVigilance and the next steps in the project. The document refers to the period 1 May 2009 – 31 August 2009. As per the agreement at Management Board level, a report on the outcome of the activities at EudraVigilance Expert Working Group and Steering Committee level (where applicable) is also provided in the attached document.

Matters for consideration

The most important developments, which could be noted during this reporting period, are described below:

- Electronic reporting compliance further increased during this period. At the level of pharmaceutical industry, 423 MAHs and 440 Sponsors of clinical trials (both at headquarter level) are now reporting electronically. At the level of the Member States, all 31 National Competent Authorities (NCAs) have been authorised to enter into production with EudraVigilance; 29 of these NCAs have electronically reported into EudraVigilance during the reporting period.
- In the context of the further roll-out of the EudraVigilance Datawarehouse and Analysis System (EVDAS), the EudraVigilance phase IIb project plan, which was adopted by the EudraVigilance Steering Committee on 8 December 2008, is continuing to be implemented.
- The work with regard to the International standardisation and harmonisation (ICH and ISO activities) also continued during the reporting period.
- The EudraVigilance Support Programme for the Member States continued during the reporting period and currently 13 NCAs receive the reports.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

Status Report on the EudraVigilance-Human Project

I Introduction

This status report provides an update on the current status of implementation of EudraVigilance-Human at the EMEA and on the EMEA initiatives to progress with the population of EudraVigilance in the field of human medicines.

II Current Status of Implementation of EudraVigilance-Human Covering the Period 1 May 2009 – 31 August 2009[1]

Activities focused on:

- The continuation of the EVDAS roll-out to the NCAs. 13 NCAs have signed up to receive bi-weekly reaction monitoring reports to aid routine pharmacovigilance from the EudraVigilance Support Programme. The EV Support programme has been delivering these reports every two weeks since 22nd December 2008.
- The practical implementation of Volume 9A part III and the monitoring of the implementation of mandatory electronic reporting of ICSRs in the EU by NCAs and MAHs for Centrally Authorised Products (CAPs).
  - All Member States are now in production with EudraVigilance for the electronic reporting of ICSRs in the post-authorisation phase.
  - Two MAHs for CAPs are not yet in production with EudraVigilance and the EMEA continues its efforts to ensure that those companies meet their obligations within the shortest possible timeframe.
  - Retrospective population of EudraVigilance continued to increase; 52,465 backlog ICSRs and SUSARs were submitted during the period 1 May 2009 – 31 August 2009 and 669,253 backlog ICSRs and SUSARs have been transmitted in total.

Three EudraVigilance Expert Working Groups were held. See Section III.1 for further details.

The three-day user training courses for the EVWEB application, the one-day training course for the EVMPD (EudraVigilance Medicinal Product Dictionary) and the three-day EVDAS training course for NCAs continued during the reporting period.

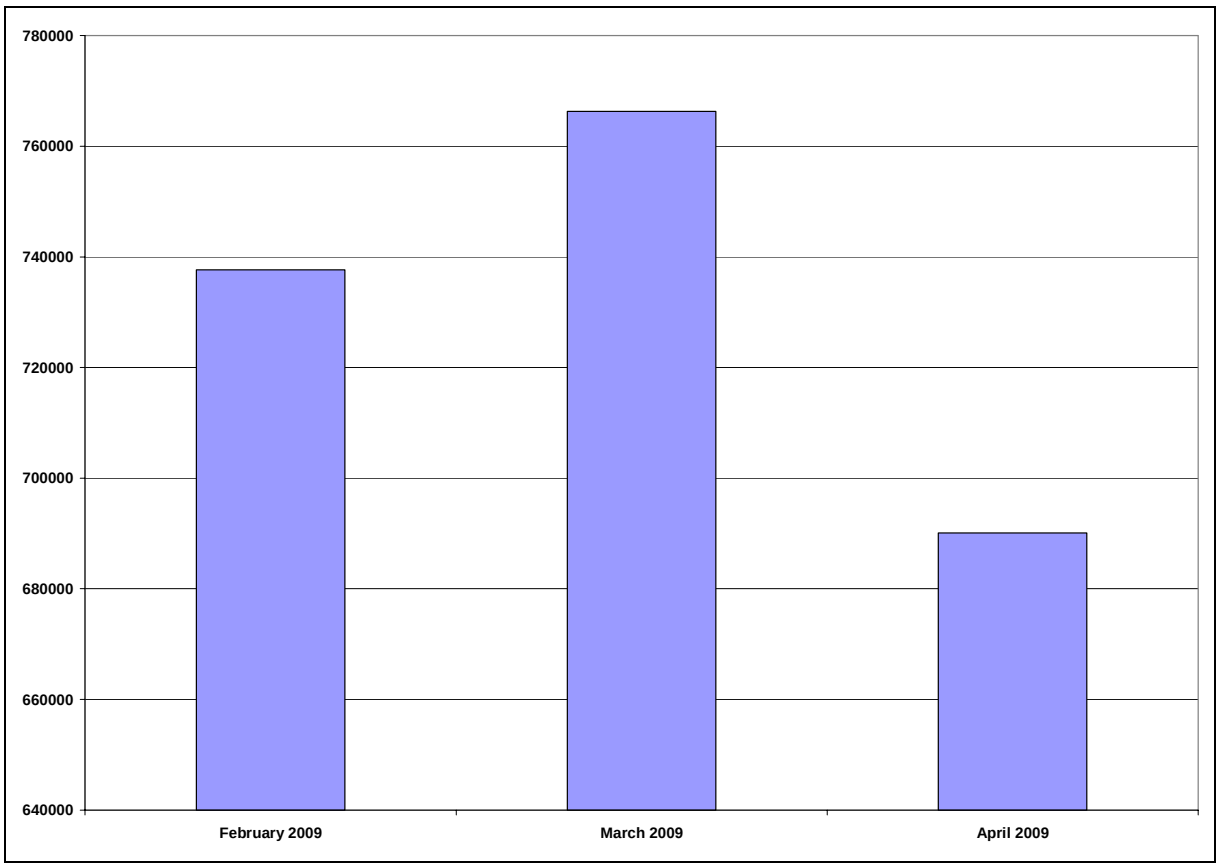
II.1 EudraVigilance Gateway

With regard to the reporting period from 1 May 2009 – 31 August 2009 a total of 2,194,058 transactions (including message disposition notifications) were performed by the EudraVigilance Gateway (production) (EVPM and EVCTM). These transactions included messages exchanged between the EMEA, pharmaceutical companies, sponsors of clinical trials and NCAs and rerouted messages to and from NCAs, sponsors of clinical trials and pharmaceutical companies.

Overall, since the establishment of the EudraVigilance Gateway in November 2001, a total of 20,715,511 transactions have been performed.

Graph 1 gives an overview of the number of transactions for the EudraVigilance Gateway (Production) from 1 May 2009 – 31 August 2009.

[1] The previous report to the Management Board referred to the period 1 February 2009 - 30 April 2009.



Graph 1: Total number of transactions performed at the level of the EudraVigilance Gateway from 1 May 2009 – 31 August 2009.

II.2 EudraVigilance Database Management System (EVDBMS)

II.2.1. E-reporting status for MAHs and Sponsors of Clinical Trials

- A total of 423 MAHs (at headquarter level) have sent reports to EVPM in the period between 1 December 2001 and 31 January 2009.
- In the period from 1 May 2009 – 31 August 2009 these MAHs reported 127,234 ICSRs to EVPM referring to 95,933 individual cases.
- In the period from 1 May 2009 – 31 August 2009 the MAHs reported a total of 11,337 backlog cases to EVPM.
- A total of 440 sponsors of clinical trials have sent reports to EVCTM in the period between 1 May 2009 – 31 August 2009.
- In the period from 1 May 2009 – 31 August 2009 these sponsors reported 22,883 ICSRs to EVCTM referring to 13,369 individual cases.
- In the period from 1 May 2009 – 31 August 2009, the Sponsors reported a total of 92 backlog cases to EVCTM.
- 16 pharmaceutical companies are currently testing with the EMEA.
- 19 pharmaceutical companies have completed testing in the period from 1 May 2009 – 31 August 2009 and are either ready to move into production or have already done so.

II.2.2. E-reporting status for NCAs

- All 31 NCAs have been authorised to enter into production with EudraVigilance.

  The status as of 30 April 2009 is:

  – 29 NCAs have reported ICSRs to EVPM (in alphabetical order of country name):

Agentur für Gesundheit und Ernährungssicherheit	Austria
Federal Agency for Medicines and Health Products	Belgium
Bulgarian Drug Agency	Bulgaria
Pharmaceutical Services	Cyprus
State Institute for Drug Control	Czech Republic
Federal Institute for Drugs and Medical Devices	Germany
Paul-Ehrlich-Institut	Germany
Danish Medicines Agency	Denmark
State Agency Of Medicines	Estonia
National Agency for Medicines	Finland
AFSSAPS	France
National Organisation for Medicines	Greece
National Institute of Pharmacy	Hungary
Lyfjastofnun (Icelandic Medicines Control Agency)	Iceland
Irish Medicines Board	Ireland
AIFA	Italy
State Agency of Medicines of the Republic of Latvia	Latvia
State Medicines Control Agency	Lithuania
Medicines Authority	Malta
College ter beoordeling van geneesmiddelen	Netherlands
Norwegian Medicines Agency	Norway
The Office For Registration of Medicinal Products	Poland
Infarmed	Portugal
ANM	Romania
State Institute for Drug Control	Slovakia
ARSZMP	Slovenia
AGEMED	Spain
Medical Products Agency	Sweden
Medicines and Healthcare Products Regulatory Agency	United Kingdom

  – Two NCAs have special arrangements:

    - The NCA for Lichtenstein (AFLUV) has a special agreement with the EMEA regarding EudraVigilance.
    - The NCA for Luxembourg, the Division de la Pharmacie et des Médicaments, has their reports transmitted by AFSSAPS.

  – **EVPM:** In the period from 1 May 2009 – 31 August 2009, the NCAs reported 55,313 ICSRs to EVPM referring to 39,114 individual cases.

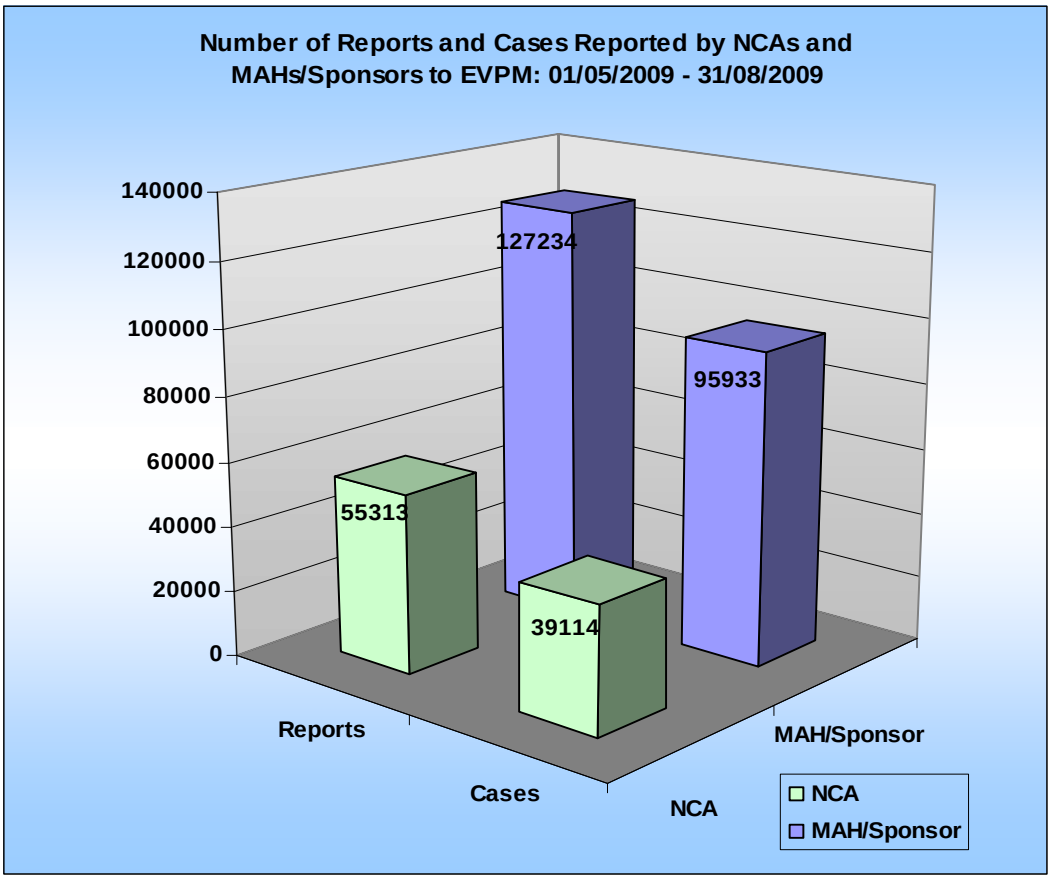
– **EVCTM:** In the period 1 May 2009 – 31 August 2009, the following 9 NCAs transmitted a collective total of 7,520 ICSRs referring to 4,107 individual cases to EVCTM:

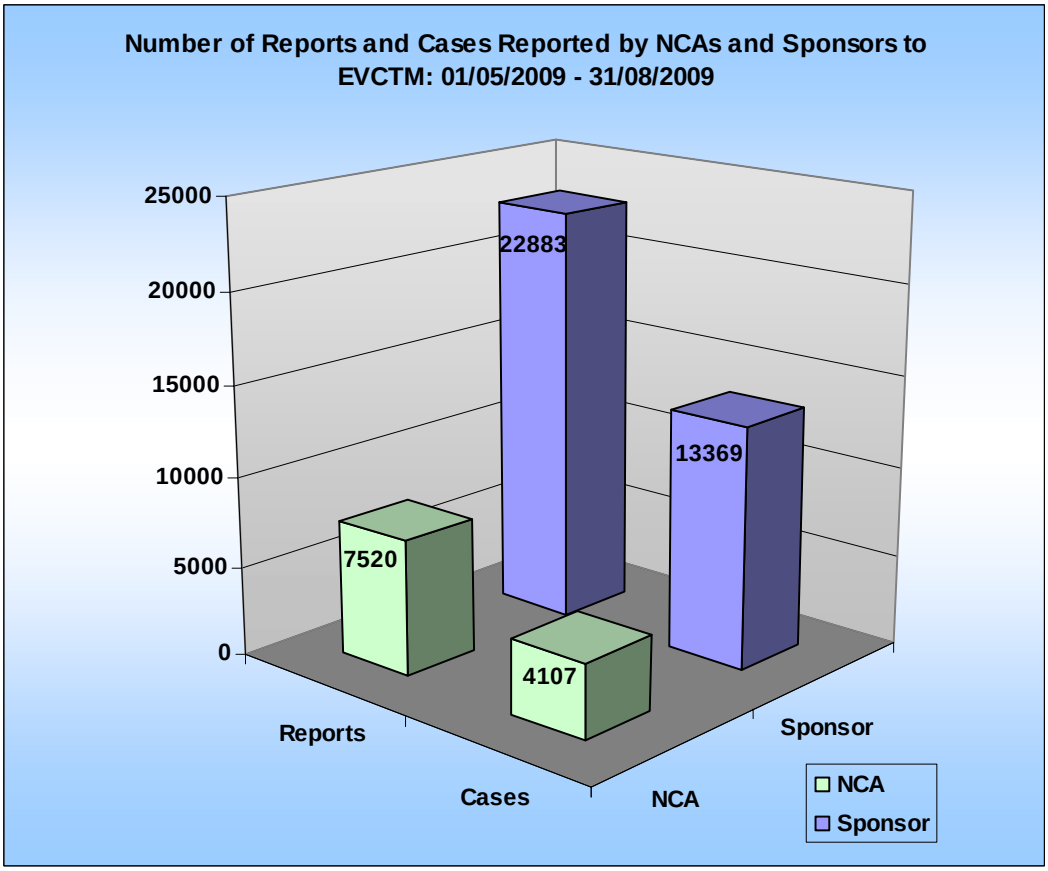
Federal Agency for Medicines and Health Products	Belgium
Danish Medicines Agency	Denmark
National Agency for Medicines	Finland
Federal Institute for Drugs and Medical Devices	Germany
Paul-Ehrlich-Institut	Germany
National Organisation for Medicines	Greece
College ter beoordeling van geneesmiddelen	Netherlands
Infarmed	Portugal
Medicines and Healthcare Products Regulatory Agency	United Kingdom

– **Backlog:** A total of 18 NCAs have transmitted a collective total of 121,7328 backlog ICSRs (both PM and CT) referring to 115,089 individual backlog cases to EudraVigilance:

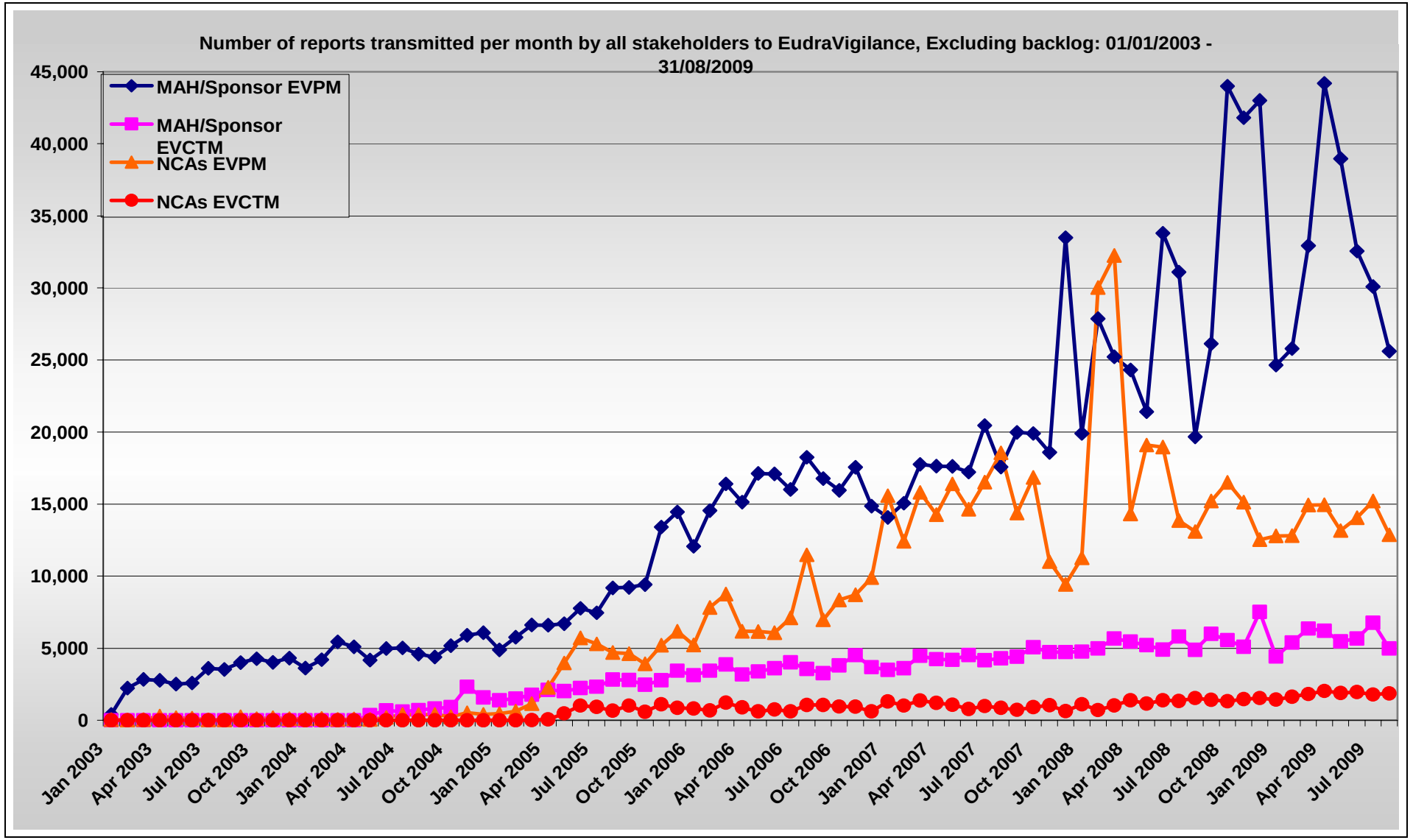
Agentur für Gesundheit und Ernährungssicherheit	Austria
Federal Agency for Medicines and Health Products	Belgium
Bulgarian Drug Agency	Bulgaria
State Institute for Drug Control	Czech Republic
Danish Medicines Agency	Denmark
Federal Institute for Drugs and Medical Devices	Germany
Paul-Ehrlich-Institut	Germany
National Organisation for Medicines	Greece
National Institute of Pharmacy	Hungary
AIFA	Italy
State Agency of Medicines of the Republic of Latvia	Latvia
State Medicines Control Agency	Lithuania
College ter beoordeling van geneesmiddelen	Netherlands
The Office For Registration of Medicinal Products	Poland
Infarmed	Portugal
State Institute for Drug Control	Slovakia
AGEMED	Spain
Medical Products Agency	Sweden

Number of reports and cases reported to EudraVigilance during the reporting period, excluding backlog





Number of reports submitted per month to EudraVigilance, excluding backlog



II.2.3. Summary of e-reporting status by all Stakeholders (NCAs, MAHs and Sponsors of Clinical Trials), excluding backlog

In the period from 1 January 2002 to 31 August 2009 a total of

- 1,872,075 ICSRs were reported to EVPM referring to 1,195,831 individual cases.
- 300,997 ICSRs were reported to EVCTM referring to 130,761 individual cases.

II.2.4. Summary of e-reporting status by all Stakeholders (NCAs, MAHs and sponsors of Clinical Trials) to EVPM split by EEA and Non-EEA, excluding backlog

In the period from 1 January 2002 to 31 August 2009 a total of

- 748,455 EEA ICSRs were reported to EVPM referring to 471,279 EEA individual cases.
- 1,123,620 non-EEA ICSRs were reported to EVPM referring to 724,552 non-EEA individual cases.

II.2.5. Summary of e-reporting status by all Stakeholders (NCAs and Sponsors of Clinical Trials) to EVCTM split by EEA and Non-EEA, excluding backlog

In the period from 1 May 2004 to 31 August 2009 a total of

- 156,607 EEA ICSRs were reported to EVCTM referring to 67,181 EEA individual cases3.
- 144,390 non-EEA ICSRs were reported to EVCTM referring to 63,580 non-EEA individual cases.

II.3 EudraVigilance Medicinal Product Dictionary (EVMPD)

During the period 1 May 2009 – 31 August 2009:

434 presentations for Investigational Medicinal Products and 7,404 presentations for Authorised Medicinal Products were entered into EVMPD.

II.4 EudraVigilance Help Desk Support Provided by the PhV-RM Sector

During the period 1 May 2009 – 31 August 2009, the EMEA PhV-RM Sector handled 2,381 written help desk requests and 175 telephone requests.

III EMEA Initiatives to Progress with the implementation of EudraVigilance in the Field of Human Medicines

III.1 Activities at EudraVigilance Expert Working Group Level

The EudraVigilance Expert Working Group (EV-EWG) met on 18 May, 29-30 June and 27 July 2009.

A summary of the most important topics discussed during these meetings is provided below:

- **EudraVigilance Phase IIb Project**

As part of the EudraVigilance Phase IIb project, the EudraVigilance Data Management call for tender is being finalised. This will be published by the end of September 2009. The EudraVigilance phase IIb deliverables are due for finalisation in October 2009.

- **Revised EudraVigilance Business Rules**

  The revised EudraVigilance Business Rules were presented to the PhVWP in May 2009 and will be sent to the Heads of Medicines Agencies for their adoption.

- **Duplicate detection and management tools**

  The new Duplicate Detection and Management tool was presented to the EV-EWG on 29 June. The EV-EWG raised a number of points which have been incorporated into the development of the tool. This tool should be made available during September 2009.

III.2 EVDAS Training for NCAs

The EVDAS training for NCAs with a professional trainer is ongoing. The training materials have been comprehensively revised and a course was held in May 2009.

III.3 Activities related to the International Standardisation Work in the context of ICH and ISO

In the context of the ISO TC 215 'Health Informatics' WG 6 'Pharmacy and Medicines Business' activities the following developments have occurred:

- The ISO ICSR project (prEN ISO 27953 – ICSRs) has entered into the ISO Draft International Standard Phase on the 30th April and is under consultation for a period of 5 months.
- The ISO Identification of Medicinal Product (IDMP) project has been recognised as a joint initiative project, involving the following stakeholders: CEN, ISO, HL7, CDISC and IHTSDO. This means that, if approved, it will be recognised by all of these bodies. This project has entered into the ISO Committee Ballot phase on the 12th May for a period of 3 months. This project encompasses the following work packages:
  - Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information (prEN ISO 11615)
  - Health informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances (prEN ISO 11238)
  - Health informatics – Identification of Medicinal Products – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs) (prEN ISO 11616)
  - Health informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration (prEN ISO 11239)
  - Health informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify Units of Measurement (prEN ISO 11240)

III.4 EudraVigilance Information Day

The 7th EudraVigilance information day has been arranged for the 4th November 2009. The programme is being prepared and will be finalised in September 2009.